Implementation Status Plans for NCTN WG Cross-Portfolio Recommendations

Dr. Jeffrey Abrams

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Cross-Portfolio Recommendations

- **Emphasize Innovative Science Driven Trials**
- **Consider Reallocation of NCTN Resources**
- **Enhance Coordinated Strategic Planning**
- **Strengthen Evaluation Criteria**
- **Optimize Steering Committee Processes**

Emphasize Innovative Science Driven Trials

NCI, NCTN Groups, CCOP Research Bases, and Steering Committees should work together to achieve the appropriate balance of innovative, biology-driven randomized phase 2 trials and larger, more resource intensive phase 3 trials in each disease portfolio

NCI Implementation Activities

- Proactively communicated message to the NCTN Groups and the Steering Committees
- Focus on the appropriate balance of innovative and more conventional trials when establishing strategic priorities for each disease
- Monitor performance through periodic strategic assessment of clinical trial portfolios

Emphasize Innovative Science Driven Trials

NCTN Groups, CCOP Research Bases, and Steering Committees should emphasize biology-driven (e.g., molecularly-driven, pathway-driven) trials that advance the science by incorporating genomics, biomarker tests and correlative science into study designs

NCI Implementation Activities

- Proactively communicated message to the NCTN Groups and the Steering Committees
- Focus on biology driven trials when establishing strategic priorities for each disease
- Monitor performance through periodic strategic assessment of clinical trial portfolios
- Scientific impact/contribution a primary criterion for cross-disease prioritization

Consider Reallocation of NCTN Resources

NCI, working with the extramural community should conduct an analysis of resource allocation across diseases, taking into account current survival rates and likely cost/benefit from additional advances

NCI Implementation Activities

- Extramural discussions did not support upfront budget allocation to each disease, concluding allocation should be driven by the science
- Cross-disease prioritization of resource-intensive trials will consider current resource allocations

Consider Reallocation of NCTN Resources

To empower innovative, biology-driven trials, additional NCI funding should be provided for correlative science studies, biomarker validation and the development of molecular classification algorithms

NCI Implementation Activities

- NCI has set aside funds annually for the Biomarker, Imaging, & Quality of Life Studies Funding Program (BIQSFP)
- Creative partnerships (e.g., Foundation for the NIH (FNIH), philanthropy, and industry partners) may provide new resources for integral, integrated and correlative studies
- R21 grant mechanism can be used to fund innovative correlative studies

Enhance Coordinated Strategic Planning

Steering Committees should increase their involvement in strategic planning and guidance for future trials in collaboration with the NCTN Groups, the CCOP Research Bases, and NCI

NCI Implementation Activities

- Continue to implement through Clinical Trials Planning Meetings
- Implement through the new disease-specific strategic priority setting process

Enhance Coordinated Strategic Planning

Greater emphasis should be placed on sharing strategic and tactical best practices across diseases in terms of trial design, accrual, preliminary data requirements, etc.

NCI Implementation Activities

- Periodic strategic assessment of NCTN trial portfolios will provide a regular venue for sharing best practices

NCI, NCTN Groups and Steering Committees should continue to pursue collaborations with international and industry partners and address barriers to these collaborations

NCI Implementation Activities

- Public-private partnerships (e.g., LungMaP trial) provide a novel template that may be useful for future collaborative trials

Strengthen Evaluation Criteria

More attention should paid to accrual challenges in proposing and approving trial concepts, balancing the importance of the clinical question with the perceived difficulty of accrual

NCI Implementation Activities

- Proactively communicated message to the NCTN Groups and the Steering Committees
- Accrual challenges currently part of evaluation criteria, but importance is being emphasized
- Accrual performance being carefully monitored by CTEP

Strengthen Evaluation Criteria

More consideration should be given to competing international and industry trials in proposing and approving trial concepts

NCI Implementation Activities

- Proactively communicated message to the NCTN Groups and the Steering Committees
- Competing trials currently part of evaluation criteria, but importance is being emphasized
- Competing trials a criterion for cross-disease prioritization

Strengthen Evaluation Criteria

Steering Committees should develop guidelines for the level and types of preliminary data required for trial concepts

NCI Implementation Activities

- NCTN Groups, Steering Committees and NCI will work together to develop disease-specific guidelines for preliminary data requirements
- Monitor implementation through periodic strategic assessment of clinical trial portfolios

Optimize Steering Committee Processes

SSCs should optimize their use of Task forces, Working Groups and Clinical Trial Planning Meetings (CTPMs)

NCI Implementation Activities

- Proactively communicated message to the NCTN Groups and the Steering Committees
- Monitor use through periodic strategic assessment of clinical trial portfolios

Thank You